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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,335	07/03/2003	Walter A. Zohmann	10012.7	5090

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EXAMINER	
CAMPBELL, VICTORIA P	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,335	ZOHMANN, WALTER A.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the initial Office Action following the Request for Continued Examination based on the 10/613335 application filed July 3, 2003. Claims 1-9 as amended January 16, 2009 are currently pending and considered below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Claims 1, 5, and 7 as amended (and therefore claims 2-4, 6, 8, and 9 as their dependents) now contain the limitations of "thirteen fenestrations" and "within three centimeters of the distal end", neither of which has support in application as filed. Applicant noted that support for these limitations was found on Page 7, lines 12-22 of the specification. However, the specification only supports "a plurality of fenestrations" which are "contained along a distance measured from the tip 14 to about 1.785 inches long the length of the needle 12". 1.785 inches is equivalent to 4.5339 centimeters, and

a plurality of fenestrations may include thirteen, but gives no support for specifically thirteen fenestrations.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 7-9 recite the limitation "said fenestrated needle" in line 6 of claim 7, line 1 of claim 8, and lines 2-3 of claim 9. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,250,035 to Smith et al in view of USPGPub 2002/0123723 to Sorenson et al.

Regarding the above claims, Smith et al teach a hollow needle (28), a needle hub (32) having a hollow interior (38) at the proximate end of the hollow needle (34), and a stylet cap (60) on a proximal end of a stylet (68), the stylet being freely movable within the needle (Col. 4, lines 43-45), wherein the stylet cap creates a releasably secure fit with the needle hub (66 received into 38). Smith et al also teach the process of identifying the dermal area of the patient (Col. 3, lines 27-29), inserting and advancing the needle into the dermal area (Col. 4, lines 63-67), withdrawing the stylet (Col. 5, lines 6-8), and injecting an anesthetic (Col. 4, lines 58-60), wherein the needle further comprises a needle hub (32), and wherein withdrawal of the stylet comprising observing a backflow of fluid (Col. 5, lines 8-15).

Smith et al fail to teach or disclose the hollow needle having thirteen fenestrations longitudinally disposed along alternate sides of the needle, within three centimeters of the distal end. However, Sorenson et al teach a plurality of fenestrations (85, of which there are fourteen, therefore thirteen is also taught) disposed on alternate sides of the needle (Fig. 1) at the distal delivery portion of the device (50), which "may extend any suitable predetermined length from the distal end 45 toward the proximal end 42 of the tubular element 25" which the examiner believes includes three centimeters (Paragraph [0027]).

Smith et al and Sorenson et al are analogous art because they are from the same field of endeavor/problem solving area of medical needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Smith et al and Sorenson et al before him or her to modify the needle of Smith et al to include the multiple distally located apertures of Sorenson et al because doing so provides a wider distribution of fluid than with a single opening while still limiting distribution to a treatment site (Sorenson et al, Paragraphs [0033] and [0036]). Therefore, it would have been obvious to combine Smith et al with Sorenson et al to obtain the invention in the instant claims.

10. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al and Sorenson et al in further view of USPGPub 2002/055715 to Young et al.

Regarding claims 3 and 4, Smith et al and Sorenson et al disclose the invention of claims 1 and 2 as described above, but fail to teach or disclose a fenestration indicator or a magnifying window on the needle hub. However, Young et al teach a needle hub (10) containing both a fenestration indicator (16) and a magnifier (17).

Regarding claims 5 and 6, Smith et al teach a hollow needle (28) being bounded by an occluded tip (72), a needle hub (32) at the proximate end of the hollow needle (34), and a stylet cap (60) on a proximal end of a stylet (68), wherein the stylet cap creates a releasably secure fit with the needle hub (66 received into 38), the stylet being freely movable within the needle (Col. 4, lines 43-45), wherein the stylet occludes the fenestrations (Fig. 11).

Smith et al fail to teach the needle having at least three longitudinally disposed fenestrations. Smith et al also fail to teach the needle hub having at least one fenestration indicator and a magnifying window.

Sorenson et al teach a plurality of fenestrations (85) disposed on alternate sides of the needle (Fig. 1). Combination of Smith et al and Sorenson et al is reasoned above.

Young et al teach a needle hub (10) containing both a fenestration indicator (16) and a magnifier (17).

Smith et al, Sorenson et al, and Young et al are analogous art because they are from the same field of endeavor/problem solving area of medical needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Smith et al, Sorenson et al, and Young et al before him or her to modify the needle system of Smith et al and Sorenson et al to include the fenestration indicator and magnifying window of Young et al because the indicator allows the user to properly orient the hub during low light conditions (Young et al, Paragraph [0031]) and the magnifier decreases the recognition time from when the fluid first enters the hub (Young et al, Abstract). Therefore, it would have been obvious to combine Smith et al and Sorenson et al with Young et al to obtain the invention in the instant claims.

Response to Arguments

11. Applicant's arguments filed January 16, 2009 regarding claims 1-9 have been fully considered but they are not persuasive.

12. Regarding applicant's argument that Sorenson et al disclose a method of distributing medicine along the *entire length* of a needle, and therefore outside of the desired treatment area, the examiner disagrees and draws applicant's attention to Paragraph [0027] of Sorenson et al which discloses that the delivery area (50) can extend any length beginning at the distal tip and extending as far as the proximal end of the delivery tube. This includes the extreme distal end, the entire length of the tube, and all potential measurements in between. Both applicant and Sorenson et al have the same goal, to "maximize an even distribution" of medication to a treatment site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763